A Report on the Volume-Quality Relationship in Hospital Tertiary Care Services in Rhode Island:

A Report on Compliance with the Hanaway Act

Prepared for

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August 16, 2002

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A number of reports in the health services and medical literature have documented that hospitals that do a high volume of some surgical procedures have better outcomes than hospitals that do a low volume of these procedures. In Rhode Island, the Hanaway Act was enacted in 1996. This legislation commissioned the Director of Health to establish quality and volume related standards to be achieved and maintained for specific tertiary health care services where peer reviewed medical and health literature establishes significant relationships between desired quality related outcomes and the volume of services provided.

Regulations on minimum volumes of services have been established in Rhode Island Hospital Regulations for neonatal intensive care services, coronary angioplasty services, coronary artery bypass graft services, and transplant programs for heart or liver transplants. The following sections summarize salient findings from examples of articles in the medical literature on the relationships between volume and quality; report the standards in Rhode Island hospital regulations; and provide comparative outcome data from other databases.

I. Neonatal Services

An example of the effects of patient volume on neonatal mortality was reported for all nonfederal California hospitals with maternity services. Mortality was measured at 28 days for all singleton births (473,209) in 1990. Infants born in hospitals with neonatal intensive care units (NICUs) with an average daily census of at least 15 patients per day had significantly lower risk adjusted mortality (Phibbs et al. 1996). The study also found that costs were no higher in these hospitals.

A hospital that operates a neonatal intensive care unit in Rhode Island is required to have a full range of capabilities and services consistent with the needs of premature infants and to upgrade these facilities as necessary to meet the recommendations of the American College of Pediatrics and the American College of Obstetricians and Gynecologists. Existing programs are required to have an average daily census of 15 neonates. New programs are required to demonstrate the expectation of meeting this volume within two years of opening the neonatal intensive care unit. Each hospital is required to maintain records of morbidity and survival rates of neonates by low birth-weight groups and to report survival data to the Rhode Island Department of Health annually. The hospital is further required to report comparative data from the Neonatal Network of the National Institute of Child Health and Human Development. If the survival rate falls below the national comparative rate by more than 25 percent, then the hospital is required to take certain corrective actions including filing a plan for correction [Part III, Section 41. Rules and Regulations for Licensing of Hospitals (R23-17-HOSP)].

Women & Infants Hospital is the only hospital in Rhode Island that offers neonatal intensive care services. For its fiscal year ending September 30, 2001, the

hospital reports that it had an average daily census of 62 neonates. This is well above the minimum. It also reports a 28-day survival rate of 96.7%–also well above the Network reported rate of 83%. (The comparative rate that would require filing a plan for correction is 79%.) Table 1 reports the rates by birth weight group compared to the Network survival rates.

Table 1
28-Day Survival Rates for Neonates

Birthweight Group	Women & Infants Hospital Survival Rate: FY 2001	Network Survival Rate: FY 2001
501 – 750 grams	56.1%	49%
751 – 1000 grams	97.4%	85%
1001 – 1250 grams	96.6%	93%
1251 – 1500 grams	96.9%	96%

II. Invasive Cardiac Services

A study of hospitals performing angioplasty services in New York state during the period, 1991-1994, included 62,670 hospital discharges. Outcomes studied included in-hospital mortality and same-stay cardiac bypass surgery. Hospitals with volumes of less than 400 per year had significantly higher mortality rates. Hospitals with volumes of less than 600 per year had significantly higher same-stay cardiac bypass surgery rates (Hannan et al. 1997).

A hospital that provides coronary angioplasty services in Rhode Island is required to have staff with appropriate professional skills and a catheterization laboratory properly equipped for these procedures. The hospital must maintain capabilities and services at a level that will meet the requirements of the American College of Cardiology and the American Heart Association. This includes having an approved coronary artery bypass graft surgery program. Existing programs are required to maintain an annual utilization rate of 400 coronary angioplasty procedures per year. New programs are required to demonstrate the expectation of achieving and maintaining this level of utilization within two years of opening a coronary angioplasty program. Hospitals with approved programs are required to report volume and outcome statistics annually. If the mortality rate for the hospital's coronary angioplasty program exceeds 75% of all hospitals doing this procedure based on data from a nationally recognized database, then the hospital is required to take corrective actions including filing a plan for correction [Part III, Section 42. Rules and Regulations for Licensing of Hospitals (R23-17-HOSP)].

Two hospitals in Rhode Island offer coronary angioplasty services. They are Rhode Island Hospital and the Miriam Hospital. Data reported by these two hospitals for the fiscal year ending September 30, 2001 are summarized in Table 2 below. It may be

seen that the mortality rate in each hospital is well below the mortality rate of 1.10% that would require a plan for correction.

Table 2

Coronary Angioplasty Utilization and Outcomes

Coronary Procedure	Rhode Island Hospital	The Miriam Hospital
Number of angiographies performed (FY 2001)	2,821	2,949
Number of angioplasties performed (FY 2001)	968	1,548
Number of emergency CABGs after angioplasty (FY 2001)	3	1
Coronary angioplasty patient in-hospital mortality (FY 2001)	0.82%	0.13%
Average angioplasty patient in-hospital mortality-New York State, 1997	0.90%	0.90%
75 percentile angioplasty patient in-hospital mortality-New York State, 1997	1.10%	1.10%

The literature on the relationship between volume and quality has led to refereed review articles on several procedures (Dudley et al. 2000) as well as recommended volume standards for health insurance programs (Birkmeyer et al. 2001). Coronary artery bypass grafts (CABGs) are typically included in such procedures. Both of the articles referenced here report that hospitals should do at least 500 CABGs per year.

A hospital in Rhode Island that has a coronary artery bypass graft surgical program is required to have staff with professional skills and equipment appropriate for these procedures. The hospital must maintain capabilities and services at a level that will meet the requirements of the Society of Thoracic Surgery, the American College of Cardiology and the American Heart Association. Existing programs are required to maintain an annual utilization rate of 500 surgical patients per year who require cardiopulmonary bypass capability, the majority of who have coronary artery bypass grafts. New programs are required to demonstrate the expectation of achieving and maintaining this level of utilization within three years of opening a coronary artery bypass graft surgical program. Hospitals with approved programs are required to report volume and outcome statistics annually. If the risk-adjusted mortality rate for the hospital's coronary artery bypass graft program exceeds 75% of all hospitals doing this procedure based on data from a nationally recognized database, then the hospital is required to take corrective actions including filing a plan for correction [Part III, Section 43. Rules and Regulations for Licensing of Hospitals (R23-17-HOSP)].

Two hospitals in Rhode Island have coronary artery bypass graft programs. They are Rhode Island Hospital and the Miriam Hospital. Data reported by these two hospitals for the fiscal year ending September 30, 2001 are summarized in Table 3 below. It may be seen that the mortality rate in each hospital is less than the expected casemix-adjusted mortality rate which is approximately equal to the median (50 percentile). By implication, the casemix-adjusted mortality rates also less than the 75 percentile rate that would require a plan of correction. Statewide rates for Pennsylvania and New York state are provided for comparison. These mortality rates are not casemix adjusted.

Table 3

Coronary Artery Bypass Program Utilization and Outcomes

Coronary Procedure	Rhode Island Hospital	The Miriam Hospital
Number of angiographies performed (FY 2001)	2,821	2,949
Number of patients who required cardiopulmonary bypass capability (FY 2001)	730	676
Number of CABG cases (FY 2001)	515	479
Elective cases	284	235
Urgent cases	212	220
Emergency cases	18	23
Salvage cases	1	1
CABG patient in-hospital mortality rate (FY 2001)	2.33%	2.09%
Expected casemix adjusted mortality rate based on STS data	4.39%	5.30%
Average CABG patient in-hospital mortality-New York State, 1998	2.15%	2.15%
75 percentile CABG patient in-hospital mortality-New York State, 1998	2.73%	2.73%
Average CABG patient in-hospital mortality-Pennsylvania, 2000	2.4%	2.4%
75 percentile CABG patient in-hospital mortality-Pennsylvania, 2000	3.2%	3.2%

III. Transplant Services

A study of all cardiac transplants done in the United States during the period, October 1987 – December 1991, found that hospitals that did less than 9 heart transplants per year had higher mortality rates that hospitals that did 9 transplants or more (Hosenpud et al. 1994). A study of liver transplantations performed in the United States between October 1, 1987 and April 30, 1994 reported that transplant centers that performed 20 or fewer procedures per year had mortality rates that were significantly higher than centers that performed more than 20 liver transplants per year (Edwards et al. 1999).

A hospital in Rhode Island that provides heart and/or liver transplant services is required to have professional staff and facilities for these procedures which conform to the bylaws of the United Network for Organ Sharing (UNOS). Existing programs for heart transplantation are required to maintain an annual utilization rate of 9 heart transplants per year. Existing programs for liver transplantation are required to maintain an annual utilization rate of 20 liver transplants per year. New programs are required to demonstrate the expectation of achieving and maintaining this level of utilization within two years of opening a transplantation program. Hospitals with approved programs are required to report volume and outcome statistics annually. Outcome statistics include risk-adjusted mortality rates at three months, one year, and three years. If the mortality rate for the hospital's transplantation program is at a level that mandates UNOS review, then the hospital is required to take corrective actions including filing a plan for correction [Part III, Section 44. Rules and Regulations for Licensing of Hospitals (R23-17-HOSP)]. No hospitals in Rhode Island have heart or liver transplantation programs at this time.

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